PHOENIX SCIENTIFIC, INC.



816 364-3777 • Fax 816 364-3778

Suitability Petition

June 1, 2000

Dockets Management Branch
HFA-305, Room 123
Food and Drug Administration
Park Building
12420 Parklawn Dr.
Rockville, MD 20857

Dear Sir or Madam:

Enclosed is a Suitability Petition submitted in accord with FFDCA Section 512 (n) (3) on behalf of Phoenix Scientific, Inc., St. Joseph, MO 64503.

The Petition concerns a minor change in the concentration of the active drug substance in a generic Pyrantel Pamoate Paste from the approved product, Strongid® (pyrantel pamoate) Paste for oral administration in horses, approved under NADA 129-831, for Pfizer. The requested change is from active drug substance 15.25 % w/w for the approved to 19.13 % w/w for the generic.

If there are any questions concerning this petition, or when you have completed your review, please call me at (816) 364-3777.

Sincerely:
Phoenix Scientific, Inc.

Robert D. Gunderson
Vice President, Regulatory Affairs



3915 S. 48th St. Terrace • St. Joseph, MO 64503
P.O. Box 8039 (64508)

PHOENIX SCIENTIFIC, INC.

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# SUITABILITY PETITION

Identification of Petitioner:

This Suitability Petition is submitted on behalf of Phoenix Scientific, Inc., (PSI) 3915 South 48th Street Terrace, St. Joseph, MO 64503 under Section 512 (n) (3) of the Federal Food, Drug, and Cosmetic Act.

Action Requested:

PSI requests permission from the Commissioner to file an Abbreviated New Animal Drug Application (ANADA) containing a different concentration of the active drug substance than the approved product. The approved product, Strongid® Paste (NADA 129-831) contains pyrantel pamoate equivalent to 15.25 % w/w pyrantel. The proposed generic will contain pyrantel pamoate equivalent to 19.13 % w/w pyrantel. The amount of active ingredients administered per dose to the animal will be the same for both products.

The indications for the use of the generic product will be the same as for the approved product. A copy of the approved product labeling is enclosed.

Statement of Grounds:

The proposed product contains the same active ingredient and has the same indications, cautions, and warnings as the approved product. Both products are for oral administration in horses. The products will differ only in the concentration of the active drug substance. The label copy will vary only as it relates to the different concentration of the active drug substance and the amount of drug product per dose.

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Environmental Impact:

The action of submitting and reviewing of this Suitability Petition will not normally be expected to have an environmental impact. Therefore, under 21 CFR 25.30(h), we request a categorical exclusion from the requirement to prepare an environmental assessment (EA), since, to the best of our knowledge, no extraordinary circumstances exist.

Economic Impact:

An "Economic Impact" analysis of this action will be provided upon request by the Commissioner.

Certification:

Attached is a statement that Phoenix Scientific, Inc. has included all information known to us, which is unfavorable to this Suitability Petition.

Approval to file an ANADA for this Pyrantel Pamoate Paste based upon this Suitability Petition is requested.

Sincerely:
Phoenix Scientific, Inc.

Robert D. Gunderson
Vice President, Regulatory Affairs

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Certificate of Inclusion of Unfavorable Information

As the Chief Executive Officer for Phoenix Scientific, Inc., I certify that no unfavorable information related to this Suitability Petition has been withheld from the attached Suitability Petition.

June 1, 2000

Kevin M. Schinze
President and CEO
Phoenix Scientific, Inc.
St. Joseph, MO 64503

3915 S. 48th St. Terrace • St. Joseph, MO 64503
P.O. Box 8039 (64508)

# Strongid® Paste

(pyrantel pamoate)

1156

pfizer

## Equine Anthelmintic

Active Ingredients: Each 20 milliliter syringe contains 3.6 grams pyrantel base in 23.6 grams of paste.

FOR VETERINARY USE ONLY

FOR ORAL USE ONLY

## Net Contents: 20 ml (23.6 g)

**INDICATIONS FOR USE:** For the removal and control of mature infections of large strongyles *(Strongylus vulgaris, S. edentatus, S. equinus)*; small strongyles; pinworms *(Oxyuris equi)*; and large roundworms *(Parascaris equorum)* in horses and ponies.

**DOSAGE:** Administer as a single oral dose of 3 milligrams pyrantel base per pound of body weight. The syringe has four weight mark increments. Each weight mark indicates the recommended dose for 300 pounds of body weight.

| Body Weight Range | Volume | mg Pyrantel Base |
|---|---|---|
| up to 300 lb | ¼ syringe (5 ml) | 900 mg |
| 301 to 600 lb | ½ syringe (10 ml) | 1800 mg |
| 601 to 900 lb | ¾ syringe (15 ml) | 2700 mg |
| 901 to 1200 lb | 1 full syringe (20 ml) | 3600 mg |

**NOTE:** Position screw-gauge over appropriate mark on plunger. Each milliliter contains 180 milligrams pyrantel base as pyrantel pamoate.

It is recommended that severely debilitated animals not be treated with this preparation.

**WARNING**

NOT FOR USE IN HORSES INTENDED FOR FOOD

KEEP OUT OF REACH OF CHILDREN

CAUTION: CONSULT YOUR VETERINARIAN FOR ASSISTANCE IN THE DIAGNOSIS, TREATMENT, AND CONTROL OF PARASITISM

**RECOMMENDED STORAGE:** STORE AT ROOM TEMPERATURE, 15°-30°C (59°-86°F)

REFER TO PACKAGE INSERT FOR COMPLETE USE DIRECTIONS

Distributed by

Pfizer AGRICULTURAL DIVISION

NEW YORK, N.Y. 10017

TAKE TIME OBSERVE LABEL DIRECTIONS

MADE IN CANADA

LOT NO. 32645

EXP. 04/96

# STRONGID® PASTE

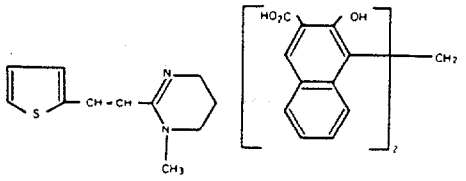
## (pyrantel pamoate)
## Equine Anthelmintic

STRONGID® PASTE is a pale yellow to buff paste containing 43.9% w/w pyrantel pamoate in an inert vehicle. Each syringe contains 3.6 grams pyrantel base in 23.6 grams (20 ml) paste. Each milliliter contains 180 milligrams pyrantel base as pyrantel pamoate.

**READ ENTIRE BROCHURE CAREFULLY BEFORE USING THIS PRODUCT**

### COMPOSITION

Pyrantel pamoate is a compound belonging to a family classified chemically as tetrahydropyrimidines. It is a yellow, water-insoluble crystalline salt of the tetrahydropyrimidine base and pamoic acid containing 34.7% base activity. The chemical structure and name are given below.




Chemical Name: (E)-1,4,5,6-tetrahydro-1-methyl-2-[2-(2-thienyl)-vinyl]-pyrimidine 4,4' methylenebis [3-hydroxy-2-naphtholate] (1:1)

### INDICATIONS FOR USE

For the removal and control of mature infections of large strongyles (***Strongylus vulgaris, S. edentatus, S. equinus***); small strongyles; pinworms (***Oxyuris equi***); and large roundworms (***Parascaris equorum***) in horses and ponies.

Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

### DOSAGE AND TREATMENT

STRONGID® PASTE is to be administered as a single oral dose of 3 milligrams pyrantel base per pound of body weight. The syringe has four weight mark increments. Each weight mark indicates the recommended dose for 300 pounds of body weight.

| Body Weight Range | DOSAGE | |
|---|---|---|
| | Volume | mg Pyrantel Base |
| up to 300 lb | 1/4 syringe (5 ml) | 900 mg |
| 301 to 600 lb | 1/2 syringe (10 ml) | 1800 mg |
| 601 to 900 lb | 3/4 syringe (15 ml) | 2700 mg |
| 901 to 1200 lb | 1 full syringe (20 ml) | 3600 mg |

NOTE: Position screw-gauge over appropriate mark on plunger. Each milliliter contains 180 milligrams pyrantel base as pyrantel pamoate.

For maximum control of parasitism, it is recommended that foals (2-8 months of age) be dosed every 4 weeks. To minimize the potential source of infection that the mare may pose to the foal, the mare should be treated 1 month prior to anticipated foaling date followed by re-treatment 10 days to 2 weeks after birth of foal. Horses and ponies over 8 months of age should be routinely dosed every 6 weeks.

### ADMINISTRATION

After removing the cap, the paste should be deposited on the dorsum of the tongue. Introduce the nozzle end of the syringe at the corner of the mouth. Direct the syringe backwards and depress the plunger to deposit the paste onto the tongue. Given in this manner, it is unlikely that rejection of the paste will occur. Raising the horse's head sometimes assists in the swallowing process. When only part of the paste has been used, replace the cap on the syringe nozzle.

### EFFICACY

Critical (worm count) studies in horses demonstrated that STRONGID® PASTE (pyrantel pamoate) administered at the recommended dosage was efficacious against mature infections of ***Strongylus vulgaris*** (>90%), ***S. edentatus*** (69%), ***S. equinus*** (>90%), ***Oxyuris equi*** (81%), ***Parascaris equorum*** (>90%), and small strongyles (>90%).

**WARNING: NOT FOR USE IN HORSES INTENDED FOR FOOD**
**KEEP OUT OF REACH OF CHILDREN**

It is recommended that severely debilitated animals not be treated with this preparation.

**RECOMMENDED STORAGE:** STORE AT ROOM TEMPERATURE, 15°-30°C (59°-86°F)

Distributed by
AGRICULTURAL DIVISION
NEW YORK, N.Y. 10017

Printed in Canada
12112-11-1

54-0196 01-90

REFER TO PACKAGE INSERT FOR COMPLETE USE DIRECTIONS

**WARNING:** NOT FOR USE IN HORSES INTENDED FOR FOOD
KEEP OUT OF REACH OF CHILDREN

FOR VETERINARY USE ONLY

FOR ORAL USE ONLY

**CAUTION**
CONSULT YOUR VETERINARIAN FOR ASSISTANCE IN THE DIAGNOSIS, TREATMENT, AND CONTROL OF PARASITISM

**RECOMMENDED STORAGE**
STORE AT ROOM TEMPERATURE, 15°–30°C (59°–86°F)

MADE IN CANADA

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**PROOF OF PURCHASE**
Pfizer Strongid Paste
1156

0 87219 71156 9

Distributed by
Pfizer **AGRICULTURAL DIVISION**
NEW YORK, N.Y. 10017

TAKE TIME OBSERVE LABEL DIRECTIONS

**DOSAGE:** Administer as a single oral dose of 3 milligrams pyrantel base per pound of body weight. The syringe has four weight mark increments. Each weight mark indicates the recommended dose for 300 pounds of body weight.

| Body Weight Range | Volume | mg Pyrantel Base |
|---|---|---|
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| 601 to 900 lb | ¾ syringe (15 ml) | 2700 mg |
| 901 to 1200 lb | 1 full syringe (20 ml) | 3600 mg |

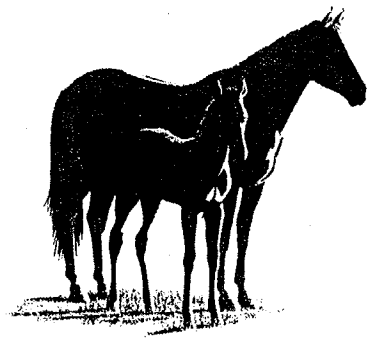
NOTE: Position screw-gauge over appropriate mark on plunger. Each milliliter contains 180 milligrams pyrantel base as pyrantel pamoate.

For maximum control of parasitism, it is recommended that foals (2-8 months of age) be dosed every 4 weeks. To minimize the potential source of infection that the mare may pose to the foal, the mare should be treated 1 month prior to anticipated foaling date followed by retreatment 10 days to 2 weeks after birth of foal. Horses and ponies over 8 months of age should be routinely dosed every 6 weeks.
It is recommended that severely debilitated animals not be treated with this preparation.

10-4345-00-1
12112-14-1

pfizer

Strongid® Paste
(pyrantel pamoate)



1156

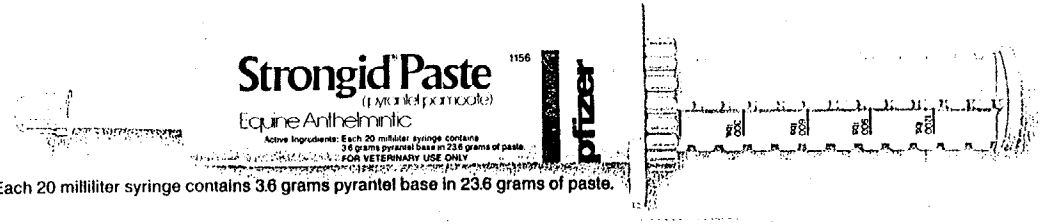
# Strongid® Paste

## (pyrantel pamoate)

## Equine Anthelmintic

Net Wt 20 ml (23.6 g)

The safe and effective horse and foal dewormer that is easy to use




Each 20 milliliter syringe contains 3.6 grams pyrantel base in 23.6 grams of paste.

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# 588

pfizer
Strongid® Paste
(pyrantel pamoate)